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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61F 2/06 — A1

(11) International Publication Number: **WO 99/51165**

(43) International Publication Date: 14 October 1999 (14.10.99)

(21) International Application Number: PCT/IE99/00019

(22) International Filing Date: 31 March 1999 (31.03.99)

(30) Priority Data:
980243 2 April 1998 (02.04.98) IE

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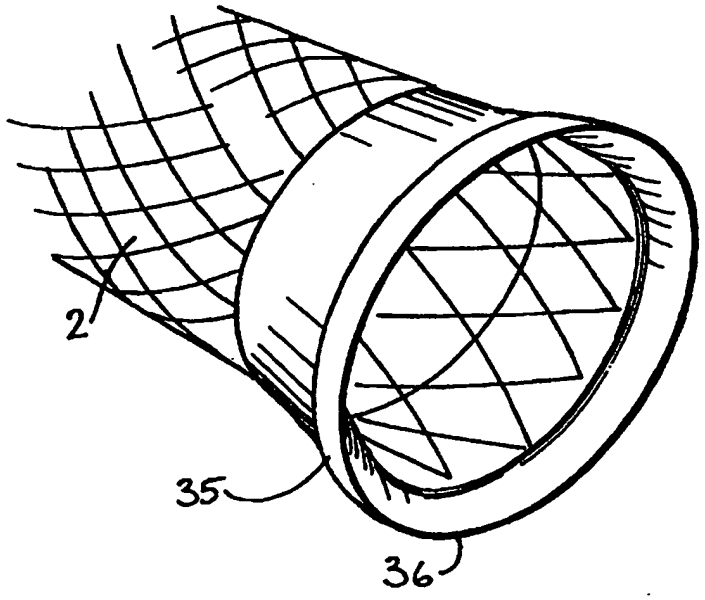
(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DE (Utility model), DK, DK (Utility model), EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published
With international search report.

(54) Title: AN IMPLANT COMPRISING A SUPPORT STRUCTURE AND A TRANSITION MATERIAL MADE OF POROUS PLASTICS MATERIAL



(57) Abstract

An implant (1, 10, 12, 15, 17, 19, 30, 34, 37, 40, 50) comprises a support (2) structure and a transition tissue bridge material (3) of porous plastic open cell structure for bedding the implant into the surrounding tissue. The support structure (2) may be a stent (1) of expansible or self-expandable material such as nitinol. The transition tissue bridge may be in the form of one or more cuffs (3) mounted on the support structure (2).

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AN IMPLANT COMPRISING A SUPPORT STRUCTURE AND A TRANSITION MATERIAL MADE OF POROUS PLASTICS MATERIAL

Introduction

The invention relates to implants and especially to stents, particularly for use in the treatment of aneurysmal disease.

Stents are devices implanted by means of a trans-catheter approach that are deployed at a vascular site to provide structural support and vessel coverage as a way to reduce the incidence of acute or progressive vessel closure. The endovascular grafting requires the placement of a prosthetic arterial graft within the lumen of the artery and the graft is attached to the internal surface of an arterial wall by an expandable stent or attachment device. The stent may be expandable by dilating a balloon on the distal end of a balloon catheter. Alternatively the stent may be a self expanding stent formed from a shape memory material such as a metallic alloy, especially nitinol.

Endoluminal stent-graft techniques for repair of abdominal aortic aneurysms (AAA) are a minimally invasive procedure as opposed to surgery. Any surgical repair procedure involves transperitoneal or retroperitoneal dissection of the aorta and replacement of the aneurysm with a prosthetic graft in the form of an artificial artery. This results in major surgery and considerable strain on the cardio-vascular system of the patient. Such grafts are shown, for example, in European Patent Specification No. 0 667 132 A3 and US Patent Specification No. 5, 695, 517. Another such graft is described in European Patent Specification No. 0 646 365.

Attachment of the stent or stents above and below the aneurysm is relatively straight-forward when the aortic aneurysm is limited to the abdominal aorta. There needs to be significant portions of normal tissue above and below the aneurysm. In addition to the problems of actually anchoring the stent, there is

also the problem of sealing the prosthesis to the arterial wall to prevent leakage. A further problem is the need to avoid the migration of the prosthesis after securement. There are thus two major problems, the prosthesis must be constructed so that it can readily be secured in position so that it is resistant to migration and secondly must be sealed sufficiently to the arterial wall at the proximal and distal sides of the aneurysm to prevent the ingress of blood between the prosthesis and the arterial wall as the ingress of blood could cause emboli to be dislodged to flow into the distal vascular system with catastrophic results such as loss of circulation in the lower limbs.

More generally there are problems in assimilating the support structure provided by an implant with surrounding body tissue. The support structure may be any item that is implanted in body tissue including a prosthesis, a pacemaker, valve and the like.

The present invention is directed towards providing an implant that will overcome at least some of these problems.

Statements of Invention

According to the invention there is provided an implant comprising a support structure and transition material mounted thereto to provide a transition bridge between the support structure and surrounding tissue, the transition material being a porous plastics material of open cell structure. Such an implant has a tissue bridge material in the form of a porous plastics material of open cell structure. This material provides a medium that tissue can readily infiltrate while being flexible in deployment and use to respond to deployment and body conditions.

In a preferred embodiment of the invention the porous plastics is a compressible foam. The advantage of this feature is that the foam material is flexible to adapt to a desired deployment and/or use configuration.

In one embodiment of the invention the support structure is a relatively soft support structure and the transition bridge material is a relatively rigid porous plastics material. In this way a relatively soft support structure can be readily accommodated and held in position.

In another embodiment of the invention the support structure is a relatively hard support structure and the transition bridge material is a relatively soft porous plastics material. This arrangement allows a relatively hard invasive support structure to be readily accommodated.

Alternatively the support structure is of intermediate stiffness and the transition bridge material is also of intermediate stiffness.

In one embodiment of the invention the support structure is a stent. In one case the stent is a self expanding stent of a shape memory material. Alternatively the stent is a balloon-expansible stent.

In one embodiment of the invention the transition bridge includes a resilient cuff of porous plastics material of open cell structure.

In this case the cuff may extend around the periphery of the implant.

The cuff may be adjacent an open end of the implant.

Alternatively a pair of cuffs are provided, mounted at each end of the implant.

In another arrangement the cuff extends along all the implant.

Preferably the cuff extends beyond the periphery of the support structure. This is advantageous in providing an improved tissue bridge.

To provide a further improved tissue bridge preferably the portions of the cuff that extend beyond the periphery of the support structure may include an anchoring/tissue keying means.

In one embodiment of the invention the implant includes keying means for keying the implant to surrounding tissue.

In one case the keying means comprises a plurality of protuberances which protrude outwardly through the transition bridge material. Alternatively or additionally the keying means comprises a plurality of keying slots.

In one arrangement the keying means is provided on the support structure. Alternatively or additionally the keying means is provided on the transition bridge.

According to one aspect of the invention there is provided a stent for endovascular techniques of the type comprising a radially expandable sleeve for mounting in an arterial passageway, characterised in that a resilient cuff of porous plastics material of open cell structure is mounted on the sleeve. This prevents the leaking of blood behind the stent.

Ideally, the cuff extends around the periphery of the sleeve. This ensures effective sealing.

Preferably the cuff is adjacent an open end of the sleeve.

The cuff may extend along all the sleeve. In this way the foamed plastics material can provide the ideal mounting.

Alternatively separate cuffs may be provided at each end of the sleeve.

In one embodiment of the invention an outer surface of the or each cuff has a plurality of protuberances formed thereon.

An outer surface of any or all the or each cuff may have a plurality of slots formed therein. This allows the cuff to resiliently accommodate changes in arterial dimensions and provides a very resilient outer surface for the cuff. It also improves compressibility for transcatheter deployment.

In another embodiment of the invention, the end surface of each cuff has a plurality of annular slots cut therein. This ensures that the cuff will accommodate at its outer end any variations in dimension so as to ensure that it will accommodate these changes and penetrate into any voids.

In another embodiment of the invention, the cuff has a plurality of internal voids. This provides additional resilience for the sleeve and facilitates compression of the cuff for deployment of the stent.

In a still further embodiment of the invention the outside diameter of the cuff varies along its length.

Brief Description of the Drawings

The invention will be more clearly understood from the following description of some embodiments thereof given by way of example only with reference to the accompanying drawings in which:-

Fig. 1 is a perspective view of a stent according to the invention;

Fig. 2 is a detail sectional view taken along the line II-II of Fig. 1;

Fig. 3 is a diagrammatic view of the stent in use in a position bridging an aneurysm;

Fig. 4 is a sectional view taken along the line IV-IV of Fig. 3;

Figs. 5(a) to (d) are sectional views of various different constructions of cuff according to the invention for use with a stent;

Fig. 6 is a sectional view of a stent with protruding barbs according to the invention;

Fig. 7 is a sectional view of another construction of stent according to the invention;

Fig. 8 is a sectional view of a further construction of stent according to the invention;

Fig. 9 is a perspective view of part of another construction of stent according to the invention;

Fig. 10 is a cross sectional view of the stent of Fig 9 according to the invention;

Fig. 11 is an elevational view of another construction of stent according to the invention; and

Fig. 12 is an elevational view of a further stent according to the invention.

Detailed Description

Referring to the drawings and initially to Figs 1 to 4 thereof, there is illustrated an implant according to the invention comprising a support framework which in this

case is of expanded metal mesh or wire frame structure. A transition material is mounted to the support structure to provide a transition bridge between the support structure and surrounding tissue. The transition material is a porous plastics material of open cell structure such as a compressible foam.

Referring to Figs 1 to 4 in this case the implant is a stent 1 and the support structure is in the form of sleeve 2. At each free end of the sleeve 2 is mounted a resilient cuff 3 manufactured from porous plastics material of open cell structure such as a foam. As will be apparent from Fig 2 each cuff 3 may have a trumpet shape.

Referring now to Fig. 3 the stent 1 is shown in use mounted within an abdominal aorta 4 at the location of an aneurysm 5. The cuffs 3 are located within the abdominal aorta 4 proximally and distally with respect to the aneurysm 5. Because the cuff 3 is made of a porous plastics material of open cell construction, it will accommodate easily within the aorta 4 to prevent any leakage past an outer wall of the stent 1. As can be seen from Fig. 4 the porous nature of each cuff 3 and inherent capacity to resiliently deform enables the cuffs 3 to accommodate even an aorta 4 of typically irregular cross-section to provide effective sealing.

Referring to Fig. 5(a) there is illustrated a cuff indicated generally by the reference number 10 having radially arranged slits 11 therein, which will allow greater compressibility and improved tissue keying.

Fig. 5(b) illustrates a cuff 12 having longitudinally arranged annular slits 13 in each end face 14 thereof which again assists in keying.

Fig. 5(c) illustrates an alternative construction of cuff indicated generally by the reference numeral 15 having a keying means provided by a dished inner portion 16, while the Fig. 5(d) illustrates a still further construction of cuff indicated

generally by the reference numeral 17, having a ribbed outer surface 18. This facilitates both radial and longitudinal compression of the cuff and tissue keying.

Referring now to Fig. 6 there is illustrated an alternative construction of cuff indicated generally by the reference numeral 19. In this case barbs 20, 21 are provided on the stent structure. These barbs 20, 21 project outwardly through the cuff 19. It will be appreciated that any tendency for movement of the prosthesis in the direction of the arrow A will cause the barbs 20, 21 to embed in the arterial wall and thus lock the prosthesis in position. In addition, the barbs 20, 21 assist in tissue keying.

Referring to Fig. 7 there is illustrated another construction of stent indicated generally by the reference numeral 30 having a foam sleeve 31 and a cuff 32 which extends over its total length. This arrangement is especially suitable to receive a tissue bridge.

Referring to Fig. 8 there is illustrated a further stent 37 according to the invention. In this case the transition tissue bridge material 38 extends over the support structure 39 and an end cuff or cuffs need not necessarily be provided.

Referring to Figs 9 and 10 there is illustrated another stent 34 according to the invention. In this case the or each cuff 35 extends beyond the periphery of the support structure 2. This is particularly advantageous in providing an improved tissue bridge as the end of the cuff is free to engage and key with surrounding tissue. In this case the cuff 35 may have a feather edge 36 to promote tissue anchoring. The thinner material is particularly readily bridged by tissue. Keying means may alternatively or additionally be provided such as those described above.

Referring now to Fig. 11 there is shown another stent indicated generally by the reference numeral 40. Parts similar to those described previously are assigned the same reference numerals. In this case the stent 40 has a bifurcated sleeve 42 covering the stent structure with a sealing cuff 3 at each opening.

Referring now to Fig. 12 a further stent is shown indicated generally by the reference numeral 50. Parts similar to those described previously are assigned the same reference numerals. In this case the stent 50 comprises a mesh sleeve 52 with a side opening 53 intermediate to the ends of the sleeve 52. A sealing cuff 3 is mounted at the opening 53. Optionally also sealing cuffs may be provided at each end of the sleeve 52 if required.

Any construction and arrangement of cuff may be provided to accommodate the particular situation in which it is required.

It will be appreciated that because of the compressibility of the foam the cuff or cuffs will be self-centering and also the cuffs will accommodate uneven surfaces and irregular shaped aortas or other vessels.

Any suitable means for attachment of the cuff on the sleeve may be provided. The use of a diisocyanante foam will give a good bond between the cuff and sleeve where the cuff is moulded around the sleeve. However, if desired, the cuff or cuffs could be made separately and then later attached to the sleeve by sewing or any other suitable method.

Conveniently the foam structure of the cuff may be designed to promote tissue ingrowth through the cuff for further enhanced sealing.

The support structure may be covered by or encapsulated by a transition bridge material.

In the invention a compressible foam is used to provide a tissue bridge between an implant such as a stent and the surrounding tissue such as a vessel being stented. This concept is beneficial for a number of other implant applications where the implant is more rigid than the surrounding tissue and does not conform readily to the surrounding tissue. The foam can provide a tissue bridge to surrounding tissue by promoting growth of cell types from the surrounding tissue. This cell growth can be propagated by seeding specific cell types or by cellular infiltration of the surrounding tissue.

The consideration of the foam as a transition material between an implant and surrounding tissue will more completely illustrate the range of potential applications. The compressible foam has the ability to blend the geometry of the implant to the vessel or tissue implant site.

In an alternative arrangement the foam could be used as a bridge between a soft implant and the surrounding tissue in a stiffer manifestation of the foam.

The foam is of a material which is biocompatible for at least medium term implantation within a living human body. This means that the material is resistant to attack by in vivo agents over extended periods of time. The material may be a polyurethane based material. There are a series of commercially available polyurethane materials that may be suitable. These are typically based on polyether or polycarbonate or silicone macroglycols together with a diisocyanate and a diol or diamine or alkanolamine or water chain extender. Examples of these are described in EP-A-461,375 and US 5,621,065. In addition, polyurethane elastomers manufactured from polycarbonate polyols as described in US 5,254,662 may also be suitable.

The most preferred material for the foam however is a biostable polycarbonate urethane article an example of which may be prepared by reaction of an isocyanate, a chain extender and a polycarbonate copolymer polyol of alkyl

carbonates. This material is described in our co-pending PCT Application No. IE98/00091, filed November 9, 1998, the entire contents of which are incorporated herein by reference. The foam may be manufactured from a block and cut into a desired shape. The foam material is preferably over moulded onto the stent. This allows the foam material to flow around and encapsulate each strut of the stent. The final geometry of the foam may be determined in the moulding step or the final geometry may be achieved in a finishing operation.

Typically the finishing operations might involve processes such as mechanical machining operations, laser machining or chemical machining.

Where the foam is manufactured in block or is moulded as a separate component it may be attached to the stent by sewing or other attachment means.

The foam is expandable and self supporting and its porous nature provides a cellular open structure which allows tissue infiltration. In addition, it is collapsible and highly compressible.

It will be appreciated that while the invention has been illustrated particularly in its application to stents, it may be applied to any suitable implant.

The invention is not limited to the embodiments hereinbefore described which may be varied in both construction and detail.

Claims

1. An implant comprising a support structure and transition material mounted thereto to provide a transition bridge between the support structure and surrounding tissue, the transition material being a porous plastics material of open cell structure.

2. An implant as claimed in claim 1 wherein the porous plastics is a compressible foam.

3. An implant as claimed in any preceding claim wherein the support structure is a relatively soft support structure and the transition bridge material is a relatively rigid porous plastics material.

4. An implant as claimed in claim 1 or 2 wherein the support structure is a relatively hard support structure and the transition bridge material is a relatively soft porous plastics material.

5. An implant as claimed in claim 1 or 2 wherein the support structure is of intermediate stiffness and the transition bridge material is also of intermediate stiffness.

6. An implant as claimed in any preceding claim wherein the support structure is a stent.

7. An implant as claimed in claim 6 wherein the stent is a self expanding stent of a shape memory material.

8. An implant as claimed in claim 6 wherein the stent is a balloon-expansible stent.

9. An implant as claimed in any preceding claim wherein the transition bridge includes a resilient cuff of porous plastics material of open cell structure.

10. An implant as claimed in claim 9 in which the cuff extends around the periphery of the support structure.

11. An implant as claimed in claim 9 or 10 in which the cuff is adjacent an open end of the support structure.

12. An implant as claimed in claim 9 or 10 wherein a pair of cuffs are provided, mounted at each end of the support structure.

13. An implant as claimed in claim 9, 10 or 12 in which the cuff extends along all the support structure.

14. An implant as claimed in any of claims 9 to 13 wherein the cuff extends beyond the periphery of the support structure.

15. An implant as claimed in claim 14 wherein the portion of the cuff that extends beyond the periphery of the support structure includes an anchoring/tissue keying means.

16. An implant as claimed in any preceding claim including keying means for keying the implant to surrounding tissue.

17. An implant as claimed in claim 15 or 16 in which the keying means comprises a plurality of protuberances which protrude outwardly through the transition bridge material.

18. An implant as claimed in any of claims 15 to 17 wherein the keying means comprises a plurality of keying slots.

19. An implant as claimed in any of claims 16 to 18 wherein the keying means is provided on the support structure.

20. An implant as claimed in any of claims 15 to 19 wherein the keying means is provided on the transition bridge.

21. An implant as claimed in any of claims 6 to 20 wherein the implant is a stent for endovascular techniques of the type comprising a radially expandable sleeve for mounting in an arterial passageway, a resilient cuff of porous plastics material of open cell structure being mounted on the sleeve.

22. A stent as claimed in claim 21 in which the cuff extends around the periphery of the sleeve.

23. A stent as claimed in claim 21 or 22 in which the cuff is adjacent an open end of the sleeve.

24. A stent as claimed in claim 21 or 22 wherein a pair of cuffs are provided, mounted at each end of the sleeve.

25. A stent as claimed in any of claims 21 to 24 in which the cuff extends along all the sleeve.

26. A stent as claimed in any of claims 21 to 25 wherein the cuff extends beyond the periphery of the sleeve.

27. A stent as claimed in claim 26 wherein the portion of the cuff that extends beyond the periphery of the support structure includes a keying means.

28. A stent as claimed in any of claims 21 to 27 including keying means for keying the stent to the surrounding tissue.

29. A stent as claimed in any of claims 21 to 28 wherein the outer surface of the sleeve has a plurality of protuberances formed thereon which protrude outwardly through the cuff.

30. A stent as claimed in any of claims 21 to 29 in which the outer surface of the or each cuff has a plurality of slots formed therein.

31. A stent as claimed in any of claims 21 to 30 in which the end surface of the or each cuff has a plurality of annular slots cut therein.

32. A stent as claimed in any of claims 21 to 31 in which the or each cuff has a plurality of internal voids.

33. A stent as claimed in any of claims 21 to 32 in which the outside diameter of the or each cuff varies along its length.

34. A stent as claimed in any of claims 21 to 33 having a side opening in a sidewall of the sleeve, a sealing cuff being mounted at said opening.

35. A stent substantially as hereinbefore described with reference to the accompanying drawings.

36. An implant substantially as hereinbefore described with reference to the accompanying drawings.

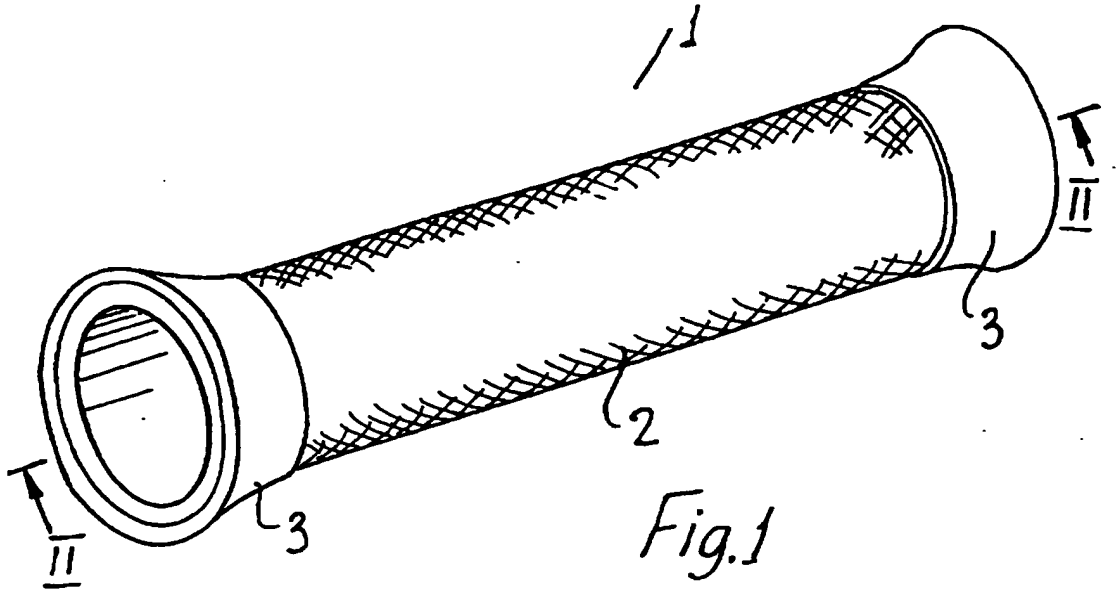

Fig.1

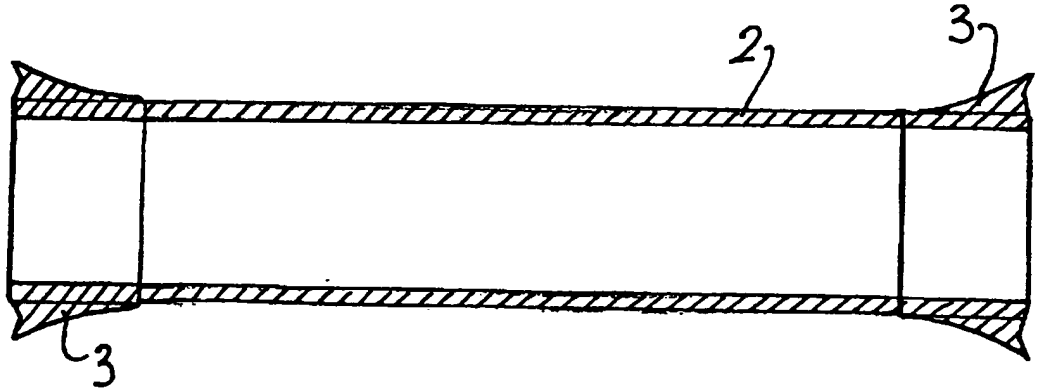

Fig.2

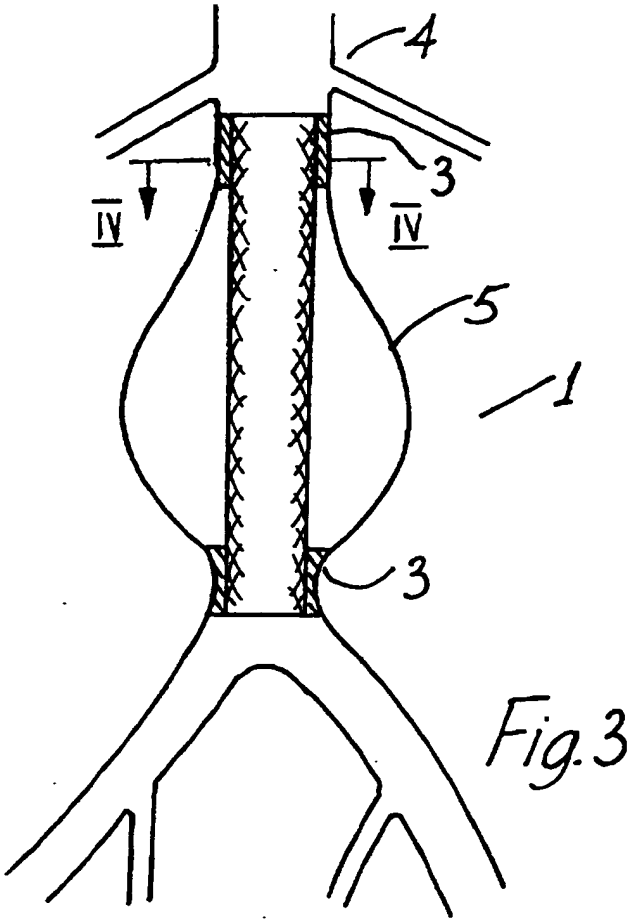

Fig.3

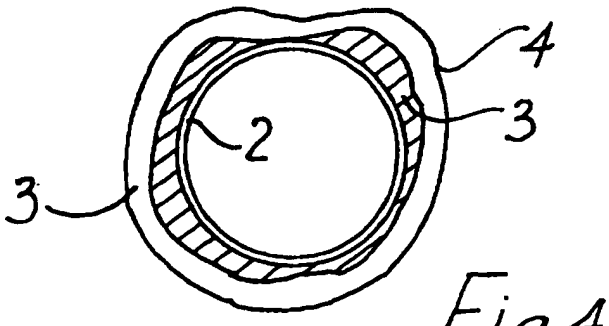

Fig.4

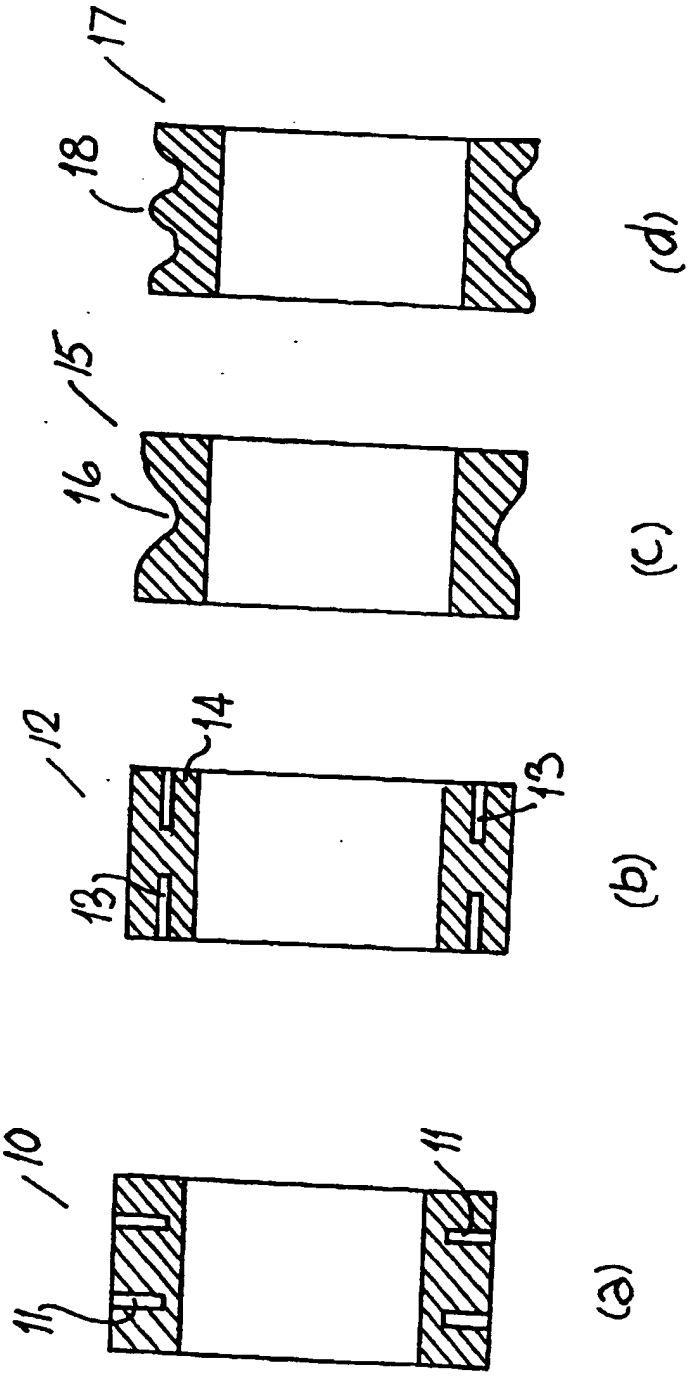

Fig.5

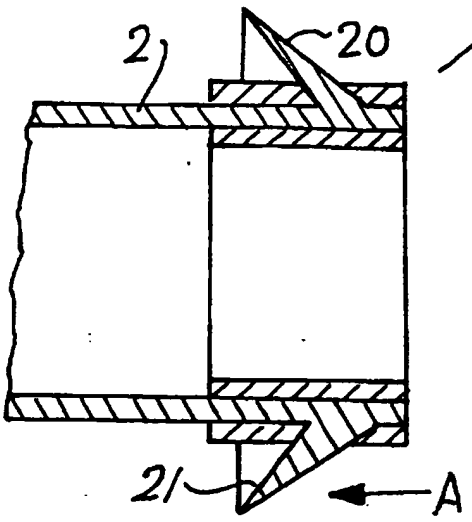

Fig. 6

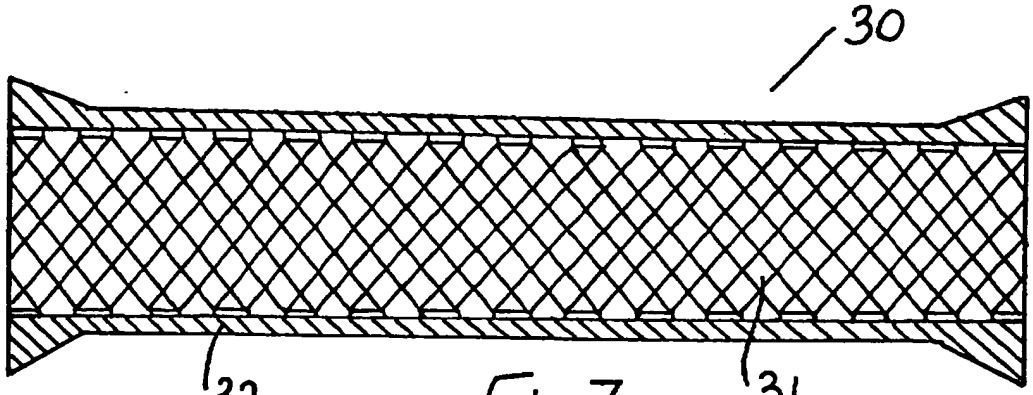

Fig. 7

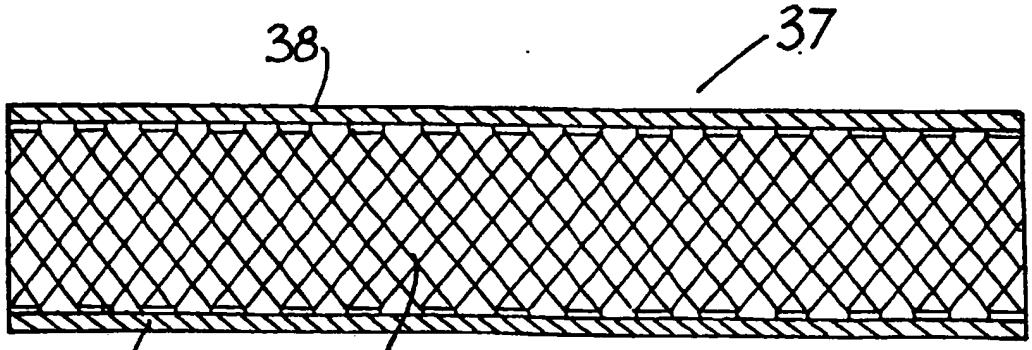

Fig. 8

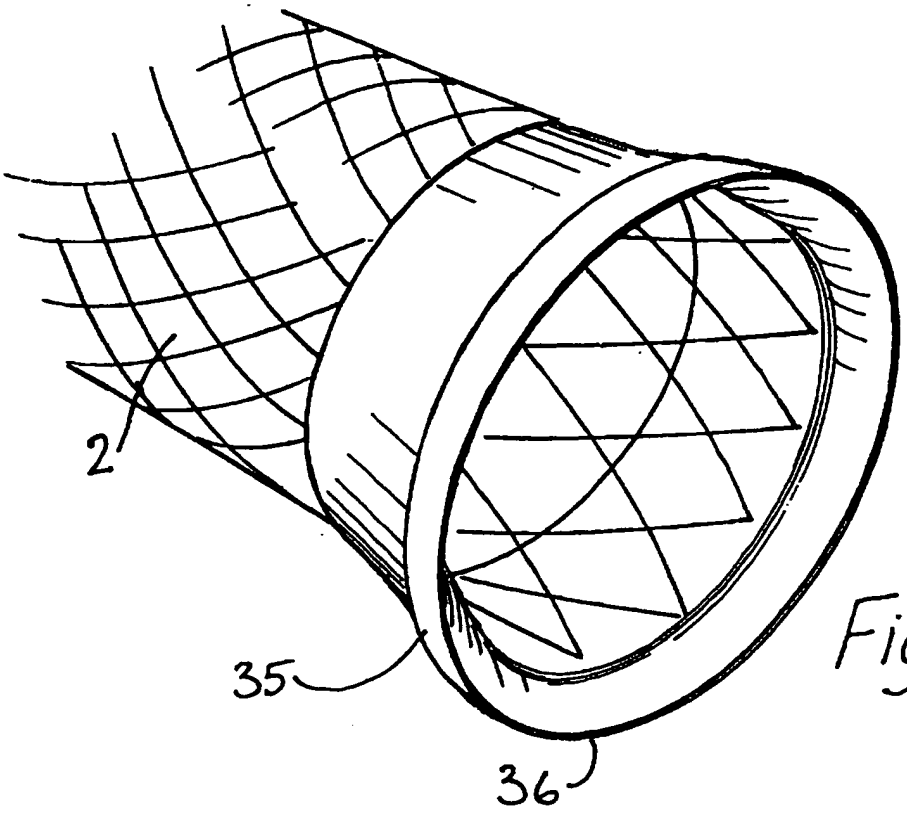

Fig. 9

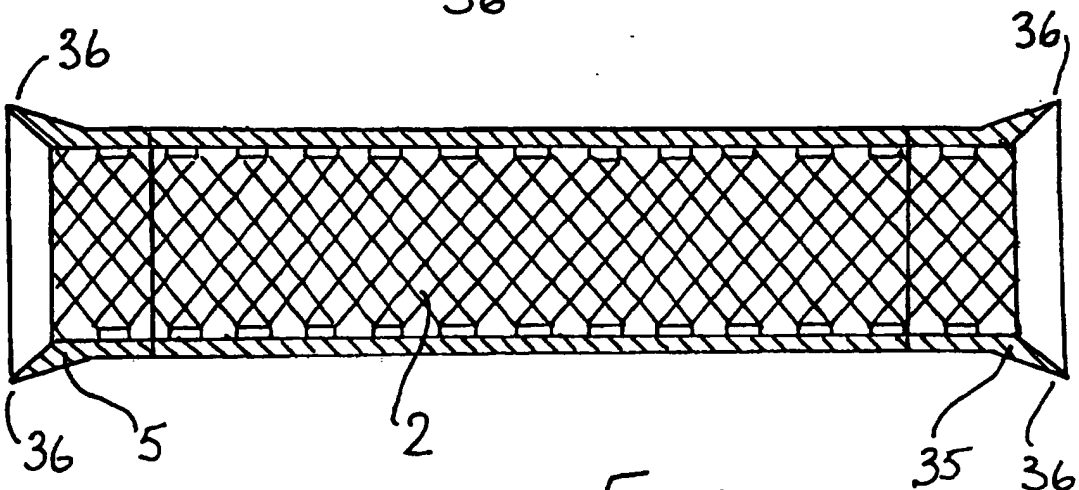

Fig. 10

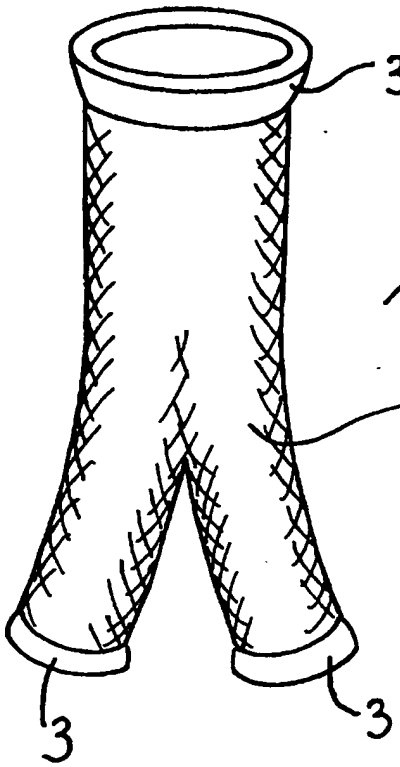

Fig. 11

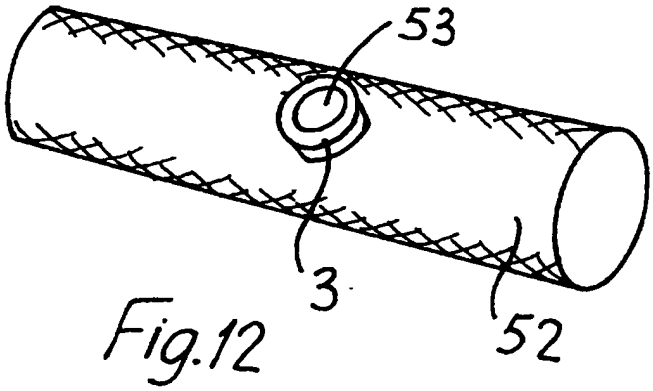

Fig. 12

INTERNATIONAL SEARCH REPORT

Interna..al Application No
PCT/IE 99/00019

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 97 09008 A (MEDTRONIC INC) 13 March 1997 (1997-03-13) page 5, line 6 - page 6, line 7; figures page 17, line 18 - page 18, line 36	1,6-28, 33,35,36
X	US 5 693 088 A (LAZARUS HARRISON M) 2 December 1997 (1997-12-02) column 4, line 12 - line 26; figures column 5, line 31 - column 6, line 38	1,6-13, 21-25, 33,35,36
A		2-5,16, 28

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
21 July 1999	29/07/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Neumann, E

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INTERNATIONAL SEARCH REPORT

Intern. nal Application No
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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A		9,10,21, 33

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